

FILED

MAR 31 2015

IN THE UNITED STATES DISTRICT COURT U.S. DISTRICT COURT-WVND
FOR THE NORTHERN DISTRICT OF WEST VIRGINIA CLARKSBURG, WV 26301

GILEAD SCIENCES, INC. and
EMORY UNIVERSITY,

Plaintiffs,

v.

MYLAN INC. and MYLAN
PHARMACEUTICALS INC.,

Defendants.

Civil Action No. 1:14-cv-99 (IMK)

JOINT STIPULATION REGARDING CLAIM CONSTRUCTION

Plaintiff Gilead Sciences, Inc.¹ and Defendants Mylan Inc. and Mylan Pharmaceuticals, Inc. hereby stipulate to the following claim constructions.

I. U.S. Patent No. 8,592,397

TERM/PHRASE	STIPULATED CONSTRUCTION
“fixed dose combination”	a unit dosage formulation comprising a fixed amount of each active pharmaceutical ingredient
“pharmaceutical dosage form”	a pharmaceutical dosage form for human administration
“less than [10%/5%] degradation of the tenofovir disoproxil fumarate or emtricitabine after 6 months”	less than [10%/5%] degradation of one or both of the TDF or FTC after 6 months
“degradation”	loss in % label strength
“dosage form is oral”	an oral dosage form for human administration
“less than 1% of impurities related to tenofovir disoproxil fumarate and	less than 1% of impurities related to each of TDF and FTC

¹ Plaintiff Gilead Sciences, Inc. is the owner of the U.S. Patent Nos. 8,592,397 and 8,716,264 (“the ‘397 and ‘264 patents”). Co-plaintiff Emory does not own, and has no interest in, the ‘397 and ‘264 patents.

TERM/PHRASE	STIPULATED CONSTRUCTION
emtricitabine"	

II. U.S. Patent No. 8,716,264

TERM/PHRASE	STIPULATED CONSTRUCTION
"fixed-dose combination"	a unit dosage formulation comprising a fixed amount of each active pharmaceutical ingredient
"less than [10%/5%] degradation of the tenofovir disoproxil fumarate and emtricitabine after six months"	less than [10%/5%] degradation of each of the TDF and FTC after 6 months
"degradation"	loss in % label strength
"40° C./70% relative humidity"	40° C./75% relative humidity
"pharmaceutical dosage form"	a pharmaceutical dosage form for human administration
"dosage form is oral"	an oral dosage form for human administration

STIPULATED and AGREED to this 19th day of February, 2015.

/s/William J. O'Brien

Thomas Krzeminski (*pro hac vice*)

thomas.krzeminski@knobbe.com

William O. Adams (*pro hac vice*)

william.adams@knobbe.com

Karen Cassidy (*pro hac vice*)

karen.cassidy@knobbe.com

KNOBBE, MARTENS, OLSON & BEAR, LLP

2040 Main Street, 14th Floor

Irvine, CA 92614

Telephone: (949) 760-0404

Facsimile: (949) 760-9502

William R. Zimmerman (*pro hac vice*)

bill.zimmerman@knobbe.com

Jay R. Deshmukh (*pro hac vice*)

jay.deshmukh@knobbe.com

Christopher C. Kennedy (*pro hac vice*)

chris.kennedy@knobbe.com

/s/Chad L. Taylor

Colleen Tracy (CT 8377)

MAYER BROWN LLP

1675 Broadway

New York, NY 10019

David B. Bassett (DB 8727)

WILMER CUTLER PICKERING HALE

AND DORR LLP

7 World Trade Center

250 Greenwich Street

New York, NY 10007

Christopher Borello (CB 6164)

FITZPATRICK, CELLA, HARPER

& SCINTO

1290 Avenue of the Americas

New York, NY 10104

KNOBBE, MARTENS, OLSON & BEAR, LLP

1717 Pennsylvania Avenue, NW, Suite 900

Washington, DC 20006

Telephone: (202) 640-6400

Facsimile: (202) 640-6401

Frank E. Simmerman, Jr. (WVSB# 3403)

Chad L. Taylor (WVSB# 10564)

SIMMERMAN LAW OFFICE, PLLC

254 E. Main St.

Clarksburg, WV 26301-2170

Local Counsel:

Gordon H. Copland (WV Bar #828)

gordon.copland@steptoe-johnson.com

William J. O'Brien (WV Bar #10549)

william.obrien@steptoe-johnson.com

STEPTOE & JOHNSON PLLC

400 White Oaks Boulevard

Bridgeport, WV 26330

Telephone: (304) 933-8000

Facsimile: (304) 933-8183

*Attorneys for Plaintiffs Gilead Sciences,
Inc. and Emory University*

Attorneys for Mylan Inc. and

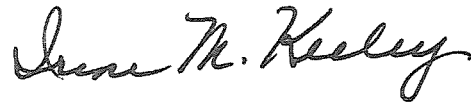
Mylan Pharmaceuticals Inc.

GILEAD SCIENCES, INC., ET AL V. MYLAN, ET AL

1:14CV99

Upon review, the stipulation is APPROVED and it is so ORDERED.

DATED: March 31, 2015

A handwritten signature in black ink, reading "Irene M. Keeley". The signature is written in a cursive, flowing style.

IRENE M. KEELEY
UNITED STATES DISTRICT JUDGE